



Attorney Docket No. 9233-63

1654  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe et al.

Confirmation No.: 2859

Serial No.: 09/873,797

Group Art Unit: 1654

Filed: June 4, 2001

For: Mixtures of Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making Same

December 23, 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Attached is a list of documents on Form PTO-1449, along with a copy of each listed document. It is requested that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. § 1.97 and Section 609 of the MPEP.

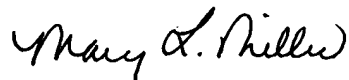
Also attached is a Declaration of James Gordon Still under 37 C.F.R. § 1.132 in which Dr. Still provides information about the slides that are included on the attached PTO Form 1449 as items 93 and 98. Although applicants provide these slides to the examiner in the interest of full disclosure in accordance with applicant's duty, it is applicants' belief that these slides are not "printed publications" as set forth in 35 U.S.C. § 102(b) and are thus not prior art to the claimed invention. Applicants base this belief on a comparison of the facts in this case as set forth in Dr. Still's Declaration with the facts set forth in *Regents of the University of California v. Howmedica, Inc.* [210 U.S.P.Q. 727 (D.N.J. 1981); *aff'd*, 676 F.2d 687 (3rd Cir. 1982); copy enclosed], in which the court determined that slides shown during an oral presentation did not constitute a "printed publication" within the meaning of 35 U.S.C. § 102(b). Because the facts reviewed by the court parallel the facts of the present application, applicants believe these slides are not prior art against the invention as claimed in the present application.

This Supplemental Information Disclosure Statement and Form PTO-1449 are

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submitted in accordance with 37 C.F.R. § 1.97(b), before the mailing of a first Office Action.  
Therefore, no fee is believed due. However, the Commissioner is hereby authorized to charge  
any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



Mary L. Miller

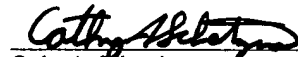
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Cathy A. Schetzina

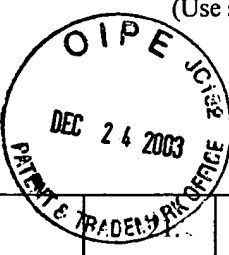
<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office				Attorney Docket Number 9233-63		Serial No. 09/873,797	
LIST OF DOCUMENTS CITED BY APPLICANT  (Use several sheets if necessary)							
				Applicants: Ekwuribe et al.			
				Filing Date June 4, 2001		Group 1651	
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document Number	Date	Country	Class	Subclass	Translation Yes   No
	1.	GB 1 492 997	11/23/77	Great Britain			
	2.	EP 0 031 567	07/08/81	EPO			
	3.	JP 1 254 699	10/11/89	Japan			
	4.	0511903	04/23/92	EP			
	5.	0483465B1	05/06/92	EPO			
	6.	WO93/01802	02/04/93	PCT			
	7.	WO95/09831	04/13/95	PCT			
	8.	EP 0 483 465	08/02/95	EP			
	9.	WO95/30641	11/16/95	PCT			
	10.	EP 0 597 007	10/16/96	EP			
	11.	EP 0 621 777	11/09/96	EP			
	12.	EP0797615B1	01/10/97	EPO			
	13.	WO98/07745	02/26/98	PCT			
	14.	WO99/32134	07/01/99	PCT			
	15.	WO99/65941	12/23/99	PCT			
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	16.	Abuchowski, A. and F. F. Davis "Soluble Polymer-Enzyme Adducts" pp. 367-383, <i>Enzymes as Drugs</i> , Ed. S. Holcenberg, John Wiley (1981)					
	17.	Agarwal et al. "Polymethacrylate-based Microparticulates of Insulin for Oral Delivery: Preparation and In Vitro Dissolution Stability in the Presence of Enzyme Inhibitors" <i>International Journal of Pharmaceutics</i> 225:31-39 (2001)					
	18.	Akiyama et al. "The Synthesis of New Derivatives of 1-β-D-Arabinofuranosylcytosine" <i>Chem. Pharm. Bull.</i> 26(3):981-984 (1978)					
	19.	Allaudeen et al. "Orally Active Insulin: A Single Insulin Conjugate Selected for Future Studies" 60th Annual Meeting of the American Diabetes Assoc., Atlanta, GA, June 2000 (Abstract)					
	20.	Anderson et al. "HIM2, a Novel Modified Insulin, has Improved Systemic Pharmacokinetics in Normal Dogs, Compared to Unmodified Insulin" American Diabetes Association 62nd Annual Meeting, June 2002 (Abstract)					

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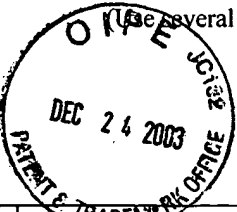
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	Ansell et al. "Application of Oligo-(14-amino-3,6,9,12-tetraoxatetradecanoic acid) Lipid Conjugates as Steric Barrier Molecules in Liposomal Formulations" <i>Bioconjugate Chem.</i> 10:653-666 (1999) ••		
22.	Aoshima et al. "N <sup>4</sup> -Behenoyl-1-β-D-Arabinofuranosylcytosine as a Potential New Antitumor Agent" <i>Cancer Research</i> 37:2481-2486 (1977) ••		
23.	Baker, D. C. et al. "Prodrugs of 9-β-D-Arabinofuranosyladenine. 1. Synthesis and Evaluation of Some 5'-(C Acyl) Derivatives" <i>J. Med. Chem.</i> 21(12):1218-1221 (1978) ••		
24.	Banting et al. "Pancreatic Extracts in the Treatment of Diabetes Mellitus: Preliminary Report" <i>Can. Med. Assoc. J.</i> 145(10):1281-1286 (1991) ••		
25.	Baudys et al. "Stabilization and Intestinal Absorption of Human Calcitonin" <i>J. Contr. Rel.</i> 39:145-51 (1996)		
26.	Baudys et al. "Synthesis and Characterization of Different Glycosylated Derivatives of Insulin" <i>Proceed. Intern. Symp. Cont. Rel. Bioactive. Mater.</i> 19:210-211 (1992) •		
27.	Block, Lawrence H. "Pharmaceutical Emulsions and Microemulsions" <i>Pharmaceutical Dosage Forms: Disperse Systems</i> Vol. 2, Ed. Lieberman et al., pp.47-109 (1996) •		
28.	Boccu et al. "Pharmacokinetic Properties of Polyethylene Glycol Derivatized Superoxide Dismutase" <i>Pharm. Res. Comm.</i> 14:113-120 (1982) ••		
29.	Bone et al. "Successful Treatment of an Insulin Dependent Rat Model of Human Type I Diabetes with Oral Active Insulin" Program and Abstracts, 4th International Workshop on Lessons from Animal Diabetes, Omiya, Japan, November 1994 (Abstract) •		
30.	Bone et al. "Successful Treatment of Type 1 Diabetes with Orally-Active Insulin: Studies in The Insulin Dependent BB/S Rat" Program and Abstracts, 55th Annual Meeting of the American Diabetes Association, Atlanta Georgia, June 1995 (Abstract) •		
31.	Brange and Volund "Insulin Analogs with Improved Pharmacokinetic Profiles" <i>Advanced Drug Delivery Reviews</i> 35:307-335 (1999) •		
32.	Brange et al. "Chemical Stability of Insulin. 1. Hydrolytic Degradation During Storage of Pharmaceutical Preparations" <i>Pharm. Res.</i> 9(6):715-726 (1992) ••		
33.	Brange et al. "Chemical Stability of Insulin. 2. Formation of Higher Molecular Weight Transformation Products During Storage of Pharmaceutical Preparations" <i>Pharm. Res.</i> 9(6):727-734 (1992) ••		
34.	Brange, J. "Galenics of Insulin: The Physico-Chemical and Pharmaceutical Aspects of Insulin and Insulin Preparations" Novo Research Institute, Denmark, pp. 18-100 (1987) ••		
35.	Chien, Y. W., Novel Drug Delivery Systems, pp. 678-679, Marcell Deffer, Inc., New York, N.Y. (1992)		
36.	Cleland et al. "Emerging Protein Delivery Methods" <i>Current Opinion in Biotechnology</i> 12:212-219 (2001) ••		
37.	Clement et al. "Effects of Multiple Doses of Orally Administered Hexyl Insulin M2 (HIM2) on Postprandial Blood Glucose (PPG) Concentrations in Type 1 Diabetic (T1) Patients" American Diabetes Association 62nd Annual Meeting, June 2002 (Poster) •		
38.	Clement et al. "Oral Insulin Product Hexyl-Insulin Monoconjugate 2 (HIM2) in Type 1 Diabetes Mellitus: The Glucose Stabilization Effects of HIM2" <i>Diabetes Technology &amp; Therapeutics</i> 4(4):459-466 (2002) •		
39.	Clement, Stephen "A Dose-Escalation Study of the Effects of Two Sequential Doses of Oral Modified Insulin on Blood Glucose Concentrations in Patients with Type 1 Diabetes Mellitus" American Diabetes Association Annual Meeting (June 25, 2001) (Abstract)		

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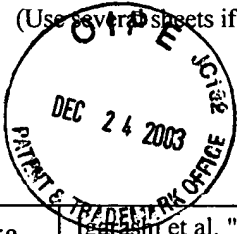
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<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office  LIST OF DOCUMENTS CITED BY APPLICANT   (Use several sheets if necessary)		Attorney Docket Number 9233-63	Serial No. 09/873,797
		Applicants: Ekwuribe et al.	
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40.	Clement, Stephen "A Dose-Escalation Study of the Effects of Two Sequential Doses of Oral Modified Insulin on Blood Glucose Concentrations in Patients with Type 1 Diabetes Mellitus" American Diabetes Association Annual Meeting (June 25, 2001) (Poster)		
41.	Conradi et al. "The Influence of Peptide Structure on Transport Across Caco-2 Cells" <i>Pharm. Res.</i> 8(12):1453-1459 (1991) ••		
42.	Coombes et al. "Biodegradable Polymeric Microparticles for Drug Delivery and Vaccine Formulation: the Surface Attachment of Hydrophilic Species Using the Concept of Poly(Ethylene Glycol) Anchoring Segments" <i>Biomaterials</i> 18:1153-1161 (1997) ••		
43.	Damge et al. "Poly(alkyl cyanoacrylate) Nanospheres for Oral Administration of Insulin" <i>Journal of Pharmaceutical Sciences</i> 86(12):1403-1409 (Dec. 1997) •		
44.	Dandona et al. "Effect of an Oral Modified Insulin on Blood Glucose Levels in Fasting and Fed Type 1 Diabetic Patients Receiving a 'Basal' Regimen of Injected Insulin" American Diabetes Association Annual Meeting (June 25, 2001) (Abstract) •		
45.	Delgado et al. "The Uses and Properties of PEG-Linked Proteins" <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 9(3,4):249-304 (1992)		
46.	Ekwuribe et al. <i>Calcitonin Drug-Oligomer Conjugates, and Uses Thereof</i> , U.S. Serial No. 10/166,355, filed 11/08/2002, including Preliminary Amendment dated 02/26/2003 and Supplemental Preliminary Amendment dated 03/31/2003 •		
47.	Ekwuribe et al. <i>Mixtures of Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making Same</i> , U.S. Serial No. 09/873,797, filed 06/04/2001 •		
48.	Ekwuribe, Nnochiri "Conjugation-Stabilized Polypeptide Compositions, Therapeutic Delivery and Diagnostic Formulations Comprising Same, and Method of Making and Using the Same" <i>Biotechnology Advances</i> 14(4):575-576 (1996) (Abstract) •		
49.	Engel et al. "Insulin: Intestinal Absorption as Water-in-Oil-in-Water Emulsions" <i>Nature</i> 219:856-857 (1968) ••		
50.	Fasano, Alessio "Innovative strategies for the oral delivery of drugs and peptides" <i>TIBTECH</i> 16:152-157 (1998) ••		
51.	Forst et al. "New Aspects on Biological Activity of C-peptide in IDDM Patients" <i>Exp. Clin. Endocrinol. Diabetes</i> 106:270-276 (1998) •		
52.	Gish et al. "Nucleic Acids. 11. Synthesis of 5'-Esters of 1-β-D-Arabinofuranosylcytosine Possessing Antileukemic and Immunosuppressive Activity" <i>J. Med. Chem.</i> 14(12):1159-1162 (1971)		
53.	Gombotz & Pettit "Biodegradable Polymers for Protein and Peptide Drug Delivery" <i>Bioconjugate Chem.</i> 6:332-351 (1995) ••		
54.	Hashimoto et al. "Synthesis of Palmitoyl Derivatives of Insulin and Their Biological Activities" <i>Pharmaceutical Research</i> 6(2):171-176 (1989) ••		
55.	Hinds et al. "Synthesis and Characterization of Poly(ethylene glycol)-Insulin Conjugates" <i>Bioconjugate Chem.</i> 11:195-201 (2000) <del>simplex</del>		
56.	Hong et al. "Nucleoside Conjugates. 7. Synthesis and Antitumor Activity of 1-β-D-Arabinofuranosylcytosine Conjugates of Ether Lipids" <i>J. Med. Chem.</i> 29:2038-2044 (1986) ••		
57.	Hostetler et al. "Synthesis and Antiretroviral Activity of Phospholipid Analogs of Azidothymidine and Other Antiviral Nucleosides" <i>The Journal of Biological Chemistry</i> 265(11):6112-6117 (1990) ••		

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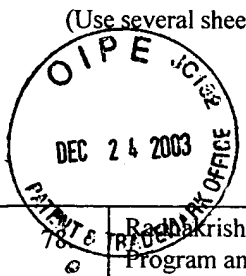
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58.	Igatah et al. "Biologically Active Peptides Conjugated with Lecithin for DDS" <i>Proceed. Intern. Symp. Cont. Rel. Bioactiv. Mater.</i> 17:367-368 (1990) /		
59.	Kemmler et al. "On the Nature and Subcellular Localization of the Proinsulin Converting Enzymes" <i>Federation Proceedings</i> 30(Abtract 924):1210Abs (1971) /		
60.	Kemmler et al. "Studies on the Conversion of Proinsulin to Insulin: I. Converison in Vitro with Trypsin and Carboxypeptidase B" <i>The Journal of Biological Chemistry</i> 246(22):6786-6791 (1971) /		
61.	King et al. "Preparation of Protein Conjugates with Alkoxypolyethylene Glycols" <i>Int. J. Peptide Protein Res.</i> 16:147-155 (1980) ••		
62.	Kipnes et al. "Control of Postprandial Plasma Glucose by an Oral Insulin Product (HIM2) in Patients with Type 2 Diabetes" <i>Emerging Treatments and Technologies</i> 26:2 (2003) /		
63.	Kipnes et al. "The Effects of an Oral Modified Insulin on Postprandial Blood Glucose Levels in Patients with Type 2 Diabetes Mellitus" American Diabetes Association Annual Meeting (June 2001) (Poster) /		
64.	Kipnes et al. "The Effects of an Oral Modified Insuling on Postprandial Blood Glucose Levels in Patients with Type 2 Diabetes" American Diabetes Association Annual Meeting (June 24, 2001) (Abstract) /		
65.	Kube, D.M. "Multitalented Proteins Play a Key Role in Therapeutics" <i>Genomics and Proteomics</i> (Sept. 2002) •		
66.	Maislos et al. "The Source of the Circulating Aggregate of Insulin in Type I Diabetic Patients is Therapeutic Insulin" <i>J. Clin. Invest.</i> 77:717-723 (1986) ••		
67.	Savva & Huang "Effect of PEG Homopolymer and Grafted Amphiphilic PEG-Palmityl on the Thermotropic Phase Behavior of 1,2-Dipalmitoyl-SN-Glycero-3-Phosphocholine Bilayer" <i>Journal of Liposome Research</i> 9(3):357-365 (1999) /		
68.	Marschutz et al. "Oral Peptide Drug Delivery: Polymer-Inhibitor Conjugates Protecting Insulin from Enzymatic Degradation In Vitro" <i>Biomaterials</i> 21:1499-1507 (2000) /		
69.	Musabayane et al. "Orally Administered, Insulin-Loaded Amidated Pectin Hydrogel Beads Sustain Plasma Concentrations of Insulin in Streptozotocin-Diabetic Rats" <i>Journal of Endocrinology</i> 164:1-6 (2000) •		
70.	Nucci et al. "The Therapeutic Value of Poly(ethylene Glycol)--Modified Proteins" <i>Ad. Drug. Del. Rev.</i> 6:133-151 (1991) ••		
71.	Oka et al. "Enhanced Intestinal Absorption of a Hydrophobic Polymer-Conjugated Protein Drug, Smancs, in an Oily Formulation" <i>Pharm. Res.</i> 7(8):852-855 (1990) ••		
72.	Pang, David C. "Bridging Gaps in Drug Discovery and Development" <i>Pharmaceutical Technology</i> 22:82-94 (Nov. 1998) •		
73.	Patel et al. "Oral Administration of Insulin By Encapsulation Within Liposomes" <i>FEBS Lett.</i> 62(1):60-63 (1976) ••		
74.	Price, JC <i>Polyethylene Glycol</i> , pp. 355-361 ••		
75.	Puskas et al. "Investigation of Chymotrypsin Digestion Profile of Orally Active Insulin Conjugate HIM2" <i>AAPS Pharm Sci.</i> 3(3) 2001 (Abstract) •		
76.	Radhakrishnan et al. "Chemical Modification of Insulin with Amphiphilic Polymers Improves Intestinal Delivery," <i>Proceed. Intl. Symp. Control. Rel. Bioact. Mater.</i> 25:124-125 (1998) (Abstract) /		
77.	Radhakrishnan et al. "Oral Delivery of Insulin: Single Selective Modification at B29-LYS With Amphiphilic Oligomer" Program and Abstracts, 1999 National Meeting of the Ameri. Assoc. Pharm. Scient., New Orleans, LA (1999) (Abstract)		

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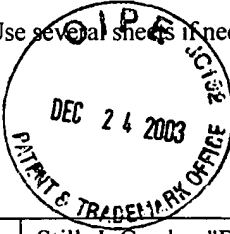
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	78.	Radhakrishnan et al. "Structure-Activity Relationship of Insulin Modified with Amphiphilic Polymers" Program and Abstracts, 1998 National Meeting of the Amer. Assoc. Pharm. Scient., San Francisco, CA <i>Pharm. Sci.</i> 1(1):S-59 (1998) (Abstract)	
	79.	Radhakrishnan et al. <i>Insulin Polypeptide-Oligomer Conjugates, Proinsulin Polypeptide-Oligomer Conjugates and Methods of Synthesizing Same</i> , U.S. Serial No. 10/389,499, filed 03/17/2003	
	80.	Ratner, R. E. et al. "Persistent Cutaneous Insulin Allergy Resulting from High-Molecular Weight Insulin Aggregates" <i>Diabetes</i> 39:728-733 (1990)	
	81.	Richards et al. "Self-Association Properties of Monomeric Insulin Analogs Under Formulation Conditions" <i>Pharmaceutical Research</i> 15(9):1434-1441 (1998)	
	82.	Robbins et al. "Antibodies to Covalent Aggregates of Insulin in Blood of Insulin-Using Diabetic Patients" <i>Diabetes</i> 36:838-841 (1987)	
	83.	Russell-Jones, G. J. "Vitamin B12 Drug Delivery" <i>Proceed. Intern. Symp. Control. Rel. Bioactive. Mater.</i> 19:102-103 (1992)	
	84.	Saffran et al. "A Model for the Study of the Oral Administration of Peptide Hormones" <i>Can J Biochem</i> 57:548-553 (1979)	
	85.	Saffran, M. et al. "A New Approach to the Oral Administration of Insulin and Other Peptide Drugs" <i>Science</i> 233:1081-1084 (1986)	
	86.	Santiago et al. "Oral Immunization of Rats with Influenza Virus M Protein (M1) Microspheres" <i>Proceed. Intern. Symp. Cont. Rel. Bioactive. Mater.</i> 19:116-117 (1992)	
	87.	Shah and Shen "Transcellular Delivery of an Insulin-Transferrin Conjugate in Enterocyte-like Caco-2 Cells" <i>Journal of Pharmaceutical Sciences</i> 85(12):1306-1311 (1996)	
	88.	Shichiri et al. "Enteral Absorption of Water-in-Oil-in-Water Insulin Emulsions in Rabbits" <i>Diabetologia</i> 10:317-321 (1974)	
	89.	Soltero et al. <i>Insulin Polypeptide-Oligomer Conjugates, Proinsulin Polypeptide-Oligomer Conjugates and Methods of Synthesizing Same</i> U.S. Serial No. 10/382,022, filed 03/05/2003	
	90.	Soltero et al. <i>Pharmaceutical Compositions of Drug-Oligomer Conjugates and Methods of Treating Diseases Therewith</i> U.S. Serial No. 10/382,069, filed 03/05/2003	
	91.	Soltero et al. <i>Pharmaceutical Compositions of Insulin Drug-Oligomer Conjugates and Methods of Treating Diseases Therewith</i> U.S. Serial No. 10/382,155, filed 03/05/2003	
	92.	Still and McAllister "Effects of Orally Active Modified Insulin in Type 1 Diabetic Patients" <i>Clinical Pharmacol. Therap.</i> 69(2):P95 (Feb. 2001) (Abstract)	
	93.	Still and McAllister "Effects of Orally Active Modified Insulin in Type I Diabetic Patients" Slide Presentation Annual Meeting of the American Society for Clinical Pharmacology & Therapeutics, Orlando, FL, March 9, 2001	
	94.	Still and McAllister "Effects of Orally Active Modified Insulin in Type I Diabetic Patients" Annual Meeting of the American Society for Clinical Pharmacology & Therapeutics, Orlando, FL, March 9, 2001 (Handout)	
	95.	Still et al. "Magnitude and Variability of Pharmacokinetic and Glucodynamic Responses to Modified Human Insulin Administered Orally to Healthy Volunteers" <i>Diabetes Research and Clinical Practice</i> 56:S77 (2002)	
	96.	Still et al. <i>Methods of Reducing Hypoglycemic Episodes in the Treatment of Diabetes Mellitus</i> , U.S. Serial No. 10/461,199, filed 06/13/2003	

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97.	Still, J. Gordon "Development of Oral Insulin: Progress and Current Status" <i>Diabetes/Metabolism Research and Reviews</i> 18(1):S29-S37 (2002)		
98.	Still, J. Gordon "Oral Insulin Development" Slide Presentation, VI International St. Barts Symposium Diabetes 2000: Therapy and Technology, London, England, May 12, 2000		
99.	Szleifer et al. "Spontaneous Liposome Formation Induced by Grafted Poly(Ethylene Oxide) Layers: Theoretical Prediction and Experimental Verification" <i>Proceedings of the National Academy of Sciences of the United States of America</i> 95(3):1032-1037 (1998)		
100.	Taniguchi et al. "Synthesis of Acyloyl Lysozyme and Improvement of its Lymphatic Transport Following Small Intestinal Administration in Rats" <i>Proceed. Intern. Symp. Control. Rel. Bioactiv. Mater.</i> 19:104-105 (1992)		
101.	Uchio et al. "Site-Specific Insulin Conjugates with Enhanced Stability and Extended Action Profile" <i>Advanced Drug Delivery Reviews</i> 35:289-306 (1999)		
102.	Wahren et al. "Role of C-peptide in Human Physiology" <i>Am. J. Physiol. Endocrinol. Metab.</i> 278:E759-E768 (2000)		
103.	Zalipsky et al. "Attachment of Drugs to Polyethylene Glycols" <i>Eur. Polym. J.</i> 19(12):1177-1183 (1983)		
104.	Ziv and Bendayan "Intestinal Absorption of Peptides Through the Enterocytes" <i>Microscopy Research and Technique</i> 49:346-352 (2000)		

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